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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,823	06/12/2002	Jonathan Griffin	SYN-128	9917

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,823	Applicant(s) GRIFFIN ET AL.	
	Examiner Agnes B Rooke	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-14, 36, 41-44, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 15-35, 37-40, 45, 46, 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 12-14, 36, 41-44, 47 and 48 are pending, and Claims 9-11, 15-35, 37-40, 45, 46, and 49-51 are withdrawn from the consideration.

Responsive to the Restriction requirement the Applicant elected Invention I of group I, Claims 1-8, 12-14, 36, 41-44, 47, and 48 without traverse, in the response filed on September 7, 2004.

This application claims priority from the PCT/GB00/02457(06/29/1999).

Improper Use Claims

Claims 41-44 provide for the use of a protein SEQ ID NO:1 (Claim 41), use of *Paecilomyces Sp.* (Claim 42 and 43), and use of recombinant micro-organism for production of a protein SEQ ID NO:1 (Claim 44), but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 41, 42, 43, and 44 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 12-14, 36, 41-44, 47 and 48 are directed to non-statutory subject matter, since the claimed insecticidal protein is not isolated or purified.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 36 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 12 states "*an insecticidal synergistic combination comprising a first protein according to claim 1 and at least one further protein.*" However, the specification does not point out "further proteins," and a proper characterization of those proteins is not included in the written description.

Claim 36 refers to FASTA search, and claims "*a FASTA opt score greater than 109.*" However, the specification does not describe how to interpret the values from the

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FASTA search, and specifically how to interpret the significance of the 109 value. See page 12, lines 1-18 of the specification. Claim 36 refers to FASTA opt score *greater than 109* when compared with SEQ ID NO:1. However, the specification lists only different FASTA opt scores that are greater than: 109, 110, 115, 117, 119, 120, 130, 140, and 150; where 150 is the last given value. See page 12, lines 1-18. Claim 36 encompasses any value larger than 109, and thus the specification does not clearly allow persons of ordinary skill in the art to recognize that the Applicant invented what is claimed.

Claim 47 states *"insecticidal protein which is capable of reacting with a monoclonal antibody raised to the protein depicted as SEQ ID NO:1."* Claim 47 does not disclosed an amino acid sequence or the structure of the insecticidal protein, which can bind to a monoclonal antibody. The insecticidal protein can be any polypeptide, and thus its structure cannot be determined, though at the same time its function is known, which is the ability to bind a monoclonal antibody. Also, the cross-reactivity could occur against a domain outside that defined by SEQ ID NO:1, and thus Claim 47 does not define the insecticidal protein.

Therefore, Claim 47 does not satisfy the written description requirement because the structure of the protein must be correlated with its function.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4 and 5 are rejected because they broaden the limitation of Claim 1.

Claims 13 and 14 recite the limitation "*combination*," however there is insufficient antecedent basis for this limitation in the claims.

Specification

The Specification is objected to because the Applicant did not cite correctly to the publications (Science and PNAS). See page 3, lines 10-17. A proper citation is required.

Conclusion

No claims are allowed. Claims 1-8, 12-14, 36, 41-44, 47, and 48 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

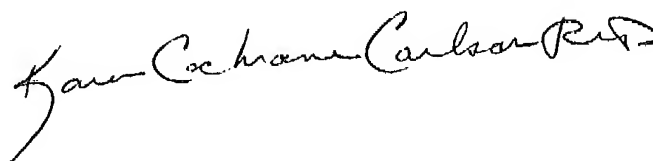
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER